Clinical Laboratory Technology Advisory Committee
Minutes of the Meeting held on September 11, 2015
Meeting held by videoconference from CDPH Richmond campus,
KP Regional Laboratory, North Hollywood, and
Telephone Bridge Line

CLTAC members participating

John Basile, Jonathan Bautista, Rhonda Becker, Marjorie Braasch, Patricia Dadone, Kathleen Doty, John Geisse, Lee Hilborne, Daniel Leighton, Armand Parada, Rebecca Rosser, Jennifer Schiffgens, Fred Ung.

CDPH staff participating

Dolapo Afolayan, Zahwa Amad, Alan Ankerstar, Karen Demby, Elsa Eleco, Ronald Harkey, Blesilda Honorio, Robert Hunter, Paul Kimsey, Tina Kruthoff, Nema Lintag, Yangzhu Long, Victoria Maxwell, Donna McCallum, Donald Miyamoto, Desiri Moret-Blyden, Martha Obeso, Janet Otey, Tammy Pahland, Nai Saechao, Judith Schlosser, Lilia Shumaker, Evan Sznol, Robert J. Thomas, Catherine C. Tolentino, Kathy Williams, Mary Frances Wogec.

Public members participating

Geraldine Albee, Barbara Brunell, Pat Bryant, Yvonne Carter, Rafael Cassata, Marian Castillo, Irene Chen, Anna Choi, Alice Crisci, Amy Daniels, Behnaz Dardashti, Kathy Davis, Ilene Disman, Imre Fischer, Cecile Giron, David Gomez, Dora Goto, Ellis Jacobs, Curtis Johnson, Margaret Knapp, Lois Langs, Carmen Maldonado, Patricia Maloney, Iris Miu, Beatrice O'Keefe, Matt Schulz, Barbara Sevilla, Shannon Smith-Crowley, Christine Vernusky, Maureen Weber, Phyllis S. Walker, Debbie Wilson-Ferguson, Annie Yang, Tammy Zinsmeister.

Welcome and general announcements

The meeting was called to order by CLTAC Chairperson Rhonda Becker at 9:05 a.m. Ms. Becker welcomed everyone, noting that it was her first meeting as committee chair and she looks forward to meeting, learning from, and collaborating with everyone. She thanked everyone for joining the meeting and supporting CLTAC's mission. She also thanked Kaiser Permanente for sponsoring the videoconference center in North Hollywood and the telephone bridge. She thanked Mary Wogec for the minutes, and introduced and welcomed Nai Saechao who will move into the role of recorder as Mary turns her focus to legislative analysis. She ended by saying that she had big shoes to fill following behind the former chair, Lorri Dean-Yoakum, who was not able to be present.

Ms. Becker conducted a roll call of CLTAC members and other participants, and noted that a quorum of CLTAC members was present for the meeting.

Remembering Les Revier

Ms. Becker announced the passing of former CLTAC member Les Revier on July 30, 2015, noting that he had been a good friend and colleague. She mentioned his passions for his family, his profession, and civil war history. He graduated in 1974 with a degree

in microbiology and began his career at the University of California, San Diego (UCSD) Medical Center. After completing his MBA, he continued to work in the laboratory, mostly in administration at UCSD, for a total of 35 years. Upon retirement he served as program director and taught clinical chemistry for the Medical Laboratory Technician program at Miramar Community College, and went on to teach clinical chemistry at UCSD. He was an active member of California Association for Medical Laboratory Technology (CAMLT) for over 30 years and served in many leadership roles since 1990. He remained active in the San Diego chapter, serving as president, distance learning author, legislative co-chair, and board member. He served many terms on the CLTAC, nominated by CAMLT. His gifts of persuasion were an asset when he testified before various State committees on several occasions to ensure the integrity of the laboratory profession and the health and safety of Californians. His hobbies included wood-working, brewing beer, and photography. His love of history led him to become a civil war reenactor. He also loved the outdoors and spent many summers hiking Yosemite, Mt. Whitney, and numerous California trails. Ms. Becker said that CLTAC will always be indebted to Les Revier and he will be missed forever.

Robert Thomas, acting chief of Laboratory Field Services (LFS), added that he had known Mr. Revier for over 25 years. Mr. Revier monitored legislation, did analysis, stayed on top of changes in the industry and, in recent years, advocated for training clinical laboratory professionals and worked with medical laboratory technician (MLT) programs as a director for training, helping that license category get its start in California. Mr. Thomas noted that LFS will also miss him.

Approval of the June, 2015 meeting minutes

Lee Hilborne moved that the minutes from the June 2015 meeting be approved as submitted. Jennifer Schiffgens seconded the motion and the minutes were approved by unanimous vote.

Department update

Dr. Paul Kimsey, Deputy Director of the Office of the State Public Health Laboratory Director (OSPHLD), gave an update on developments in the California Department of Public Health (CDPH). He announced that on September 10, 2015, the California State Auditor (CSA) released their report on the follow-up audit to the original 2008 audit of LFS. The report made nine recommendations, and the Department saw a draft of the report and provided initial responses to each of the recommendations. The Department agrees with all the recommendations and has made progress on some of the areas pointed out in the report, much of which is similar to the 2008 audit. The Department agrees that it has not completed its work with regard to the findings from the 2008 report, and the new report has given more specific direction on a number of the recommendations. The Department will respond to the CSA report in 60 days, in six months, and in one year. Dr. Kimsey said that he would speak in more detail at the December meeting, at which time the Department will have provided its 60 day response. Dr. Kimsey noted that while there would not be much time to discuss the matter in great detail at the present meeting, he would take questions after reporting on the next item.

Dr. Kimsey reported that Senate Bill (SB) 75 passed the California legislature. Existing law at Section §1220 of the California Business and Professions Code (BPC) requires a clinical laboratory that performs tests or examinations that are not classified as waived under CLIA to establish and maintain a quality control program that meets specified CLIA standards. This bill amends BPC §1220 to provide that the quality control program may include the clinical laboratory's use of an alternative quality testing procedure recognized by the Centers for Medicare and Medicaid Services, including equivalent quality control procedures (EQC) or an Individual Quality Control Plan (IQCP). Dr. Kimsey acknowledged the contributions of the Department and individuals who provided technical assistance to harmonize federal requirements for quality control with California law. As of July 1, EQC is an option in California; on January 1, 2016, IQCP will replace EQC as an option.

Ms. Becker asked if the Department's response to the audit report is an interactive process.

Dr. Kimsey responded that the CSA auditors act as government oversight and in the report they direct LFS to respond to their recommendations. The Department agrees with those recommendations and will proceed to address them. He also noted that some recommendations appear to be open-ended, so it is not clear that completing certain tasks would resolve those issues. He ended by saying that dialogue with the auditors is an interactive process.

Dr. Hilborne noted that some of the recommendations are directive. He suggested that the CLTAC could work with the Department on some of these recommendations to make the audit recommendations an opportunity and asked if the process would allow for that.

Dr. Kimsey responded that he believed the process would allow for CLTAC involvement, as the Committee advises the Department on technical issues, and said that the Department would welcome CLTAC involvement. He cautioned that since the report only came out the day before the meeting, the Department has not yet determined how the CLTAC could be incorporated. He asked that members who want to participate in the process contact himself or the Department. He noted that after 60 days, the Department will be able to show what progress has been made and give specific information about some of the agreements. He also noted that the audit findings are recommendations, and that some of the issues cannot be resolved within a year.

Jennifer Schiffgens asked if EQC would be replaced by IQCP in January. Dr. Kimsey confirmed that IQCP would replace EQC as an option on January 1, 2016. Ms. Schiffgens asked about plans for state surveyors to inspect laboratories under IQCP, what they would be looking for, and what the expectations would be.

Dr. Kimsey deferred to Donna McCallum, LFS Section Chief for CLIA, and LFS for comment on specific issues, but commented that the overall policy goal is to harmonize

so that State inspectors do not do things differently than federal investigators, as was previously the case.

Ms. McCallum replied that under the CLIA regulations, IQCP will replace EQC as of January 1, 2016, but that currently EQC is acceptable. When CLIA inspectors look at IQCP, they will look at risk assessment, quality control, and quality assessment. She invited those unfamiliar with the three items comprised by IQCP to visit the CMS website, which includes an IQCP workbook that explains the process. She reported that there would be a period of education, but after that period is over, everyone would have the option of using IQCP or defaulting back to current CLIA regulations. After January 1 it is not possible to go back to EQC, but laboratories can go back to the default regulation.

Ms. Schiffgens reported that the American Society for Microbiology (ASM) had written a letter to CMS arguing that IQCP should not apply to microbiology and they should be able to do what they have been doing all along. She asked if the Department had any comment.

Ms. McCallum responded that ASM has the option of defaulting to CLIA regulations. She expressed doubt that anything would change given the amount of work put into the legislation and the political and fiscal aspects. Mr. Thomas asked Ms. McCallum to confirm that the only area in which EQC or IQCP do not apply is histopathology. Ms. McCallum confirmed that histopathology is the only area. She invited people to go to the CLIA website and voice their concerns, as there is a workgroup that will respond to all inquiries.

Update from legal counsel

Tammy Pahland, House Counsel for LFS, reported that a tracking log is now available for the nine regulation packages assigned to LFS, thanks to the collaborative efforts of the Office of Legal Services (OLS), LFS, and the CDPH Director's Office. She noted that regulations are a high priority for the Department.

Ms. Pahland introduced Evan Sznol, an attorney who was recently assigned to help LFS with regulations, and asked him to introduce himself. Mr. Sznol said that he graduated from Johns Hopkins University with a degree in cognitive science in 2006, graduated from UC Hastings College of the Law in 2014, and started working for the OLS in August 2015. Ms. Pahland thanked him, reporting that his addition to the staff will be of great assistance to the program. He will draft regulations, working with subject matter experts in LFS, and help move the regulations packages through the approval process.

Ms. Pahland reported that OLS had also assigned another attorney, Bridget Jones, to work with LFS on regulations. Ms. Jones has been with OLS for three years and has worked on various complex packages dealing with radiological health. She has a BS from UC Davis, a JD from McGeorge School of Law, and a master's degree in Law and Intellectual Property from Santa Clara University; she is a patent scientist and

researcher in biotechnology and her technical background will be very helpful in her work with LFS. Ms. Jones will be assigned to the personnel regulations package and other items. Mr. Sznol will be working on sperm washing regulations, the repeal of Title 17 of the California Code of Regulations (17 CCR) §1050, the adoption of new standards, and tissue bank and tissue storage regulations.

Ms. Becker thanked Ms. Pahland for the tracking log, commenting that it was a useful tool. She asked if it would be updated as items were added and deleted as the Department achieved goals and added more regulations.

Ms. Pahland responded that it is a fluid document, and assignments and timelines will change and packages will be added or completed.

Ms. Becker asked how the timelines for the packages are determined.

Ms. Pahland responded that the start date is when a package is first developed and the regulation process team, including program staff, legal staff, and staff from the Office of Regulations (OOR), meet and start drafting the package. OOR follows a formula to assign subsequent target dates, estimating typically a year and a half to two years between the beginning date and the date for filing with the Secretary of State (SOS). The dates on the chart are estimates. Drafts of the first four packages should be completed by the end of this year. Work on the regulations packages and the 2003 CLIA crosswalk has been prioritized based on need and importance.

Dr. Hilborne noted that the CSA report recommends statutory changes that would impact these regulatory changes and asked how LFS would work in parallel with that.

Ms. Pahland responded that the audit addressed repealing regulations that were outdated. LFS is working to repeal 17 CCR §1050, and is coordinating that effort with the CLIA crosswalk.

Dr. Hilborne asked if the Department’s 60 day response might influence this.

Dr. Kimsey responded in the affirmative, noting that the audit recommendations in both the 2008 audit report and the current report dealt with regulations, and that the Department has prioritized regulations and added resources.

Ms. Becker said that she understood the audit to target facility licensing standards rather than personnel standards, but noted that work on personnel standards is still pertinent.

Ms. Pahland said that it is. She noted that there are bills in process or already passed that will affect the personnel standards package, which would be addressed later in the agenda. Because that package is so large and comprehensive there will probably be changes right up to the day it is submitted for approval.

LFS update

Mr. Thomas congratulated Rhonda Becker on her election and appointment as the chair of CLTAC. He stated that the continued input received by CLTAC members and attendees is important in assisting LFS with selecting the agenda items.

He announced that LFS has seven new staff members. Nai Saechao is now the assistant to the branch chief. He will be assisting with the CLTAC agenda, writing the minutes, sending out announcements, assisting with web site changes and updates, handling staff time reports, and assisting with tracking Public Records Act requests and other correspondence. Sarah Rutschmann is an analyst who will be serving as the LFS Human Resources liaison. She will be working to revise professional and technical duty statements for LFS and consult with management and staff regarding hiring practices, rules and regulations, bargaining unit contracts, duty statements, benefits, payroll duties, and related employment issues. She will also help to develop and implement a plan for recruitment and retention and new employee training orientation and training policies. She transferred to LFS from the Office of Statewide Health Planning and Development. Mr. Thomas said that section chiefs would be making announcements in their reports for the other new staff members.

Mr. Thomas reported that LFS intended to work with the CLTAC on agenda items to make the agenda more descriptive. LFS is also moving to presenting the previous quarter's statistics as handouts. The goal is to have more consistent and readily available management reports to enable LFS to determine where to assign resources. LFS is also working with the CDPH ITSD division to improve report generation in real-time.

Mr. Thomas reported that LFS was asked at the last CLTAC to provide an update on SB 622. Mary Wogec, who will be taking more responsibility on preparing legislative analyses for internal review, will report on the current season's legislation at this meeting. He noted that LFS was close to going live with a new online personnel license application system, and Tina Kruthoff, the Assistant Chief for the Office of the Public Health Laboratory Director, would be reporting on this new system and other upcoming technological improvements.

Mr. Thomas reported that an ongoing topic on the agenda had been the CLTAC subcommittee report on CLIA 2003 changes and comparison with California law. At the September 2014 CLTAC meeting, the CLTAC chair, Lorri Dean-Yoakum said that a discussion and vote on the subcommittee's verbal report would wait for a written document. LFS completed the draft document and the item will be discussed later in the meeting. He then read and reiterated the Department's original charge to the subcommittee as follows:

> The subcommittee to review CLIA 2003 is charged with evaluating changes made in federal law since January 1, 1994. Any changes made in CLIA 2003 should be listed and evaluated as to whether the change is now more stringent than current state law or less stringent. Changes that are equivalent and that would not impact state law need not be addressed. We would ask that the

subcommittee then make recommendations in the form of a position paper whether the state should adopt or reject any of these changes in CLIA. This position paper would be reviewed by the entire CLTAC and then given to the Department for review.

Mr. Thomas reported that there was a great improvement in clearing the backlog of renewals that was discussed at the last CLTAC meeting. In June, LFS was receiving four to five complaints a day from persons requesting assistance with license renewal. Currently, there are four to five inquiries per week, mainly on technical issues or asking for information about the program.

Mr. Thomas noted that a recurring topic at past CLTAC meetings had been LFS efforts at recruitment and retention of professional Examiner staff in LFS. A sustained 35% vacancy rate for examiners has impacted the ability of LFS to meet the obligation of inspecting every laboratory at least once every two years. LFS is working to improve the pay disparity, offering education and training incentives, and working with coaches from California State University to make quality improvement (QI) a part of the Department's culture. He said that LFS also welcomes ideas and advice from CLTAC.

Dr. Hilborne said that receiving the statistics in advance would allow the CLTAC to focus on matters that required attention during meetings. He also suggested that an upcoming opportunity for recruitment would be the annual meeting of the ASCP to be held in Long Beach in October.

Mr. Thomas reported that LFS is working with ITSD to improve LFS' reporting process, and that it was important to get that kind of feedback.

Ms. Kruthoff reported that at the June meeting, LFS was processing renewals approximately 45 days after receipt. The renewal unit is now processing them between 15 and 20 days after receipt. Since it t takes about 10 days for our mail to be processed, this represents a significant improvement, and she congratulated the renewal unit on a wonderful job.

Ms. Schiffgens asked if there is an exemptions process, if perhaps someone's check was cashed and a long time had gone by but the renewal had not been processed, and if there could be a quality assurance process to ascertain if something got lost in the mail or was otherwise misplaced.

Ms. Kruthoff replied that personnel renewals are currently processing by expiration date and renewals with an expiration date coming soon are set aside for expedited processing. One person is specifically assigned to that, and this has decreased complaints. The others are processed in the order that they are received. Until the online renewal system is in place, not much more can be done to improve processing time. The capacity to track documents in the mail system does not currently exist.

Mr. Thomas added that mail coming to the Richmond campus first passes through the

central mail room and that it takes some days for this to happen. He reiterated that until the online system is in place, not much more could be done to improve processing time.

Dr. Hilborne said that he thought LFS had made incredible progress, but suggested prioritizing the electronic system. Ms. Schiffgens added that this would also help to improve the perception of LFS held by the stakeholders and would ultimately aid in recruitment.

Bob Hunter, Examiner for LFS, asked Mr. Thomas if there would be discussion on the CSA audit report.

Dr. Kimsey replied that it was discussed generically earlier, but offered to discuss it further.

Mr. Hunter replied that he had looked through the report and felt that the CSA auditors might have missed the mark on many things; in particular, the report seemed to come from a federal perspective and not a state one.

Dr. Kimsey replied that it was important to look at the Department's initial response to the audit, which begins on p. 47 of the report. He noted that the Department received a draft of the report before it was released, and commented on each of the recommendations. As the auditors are a State regulatory body, their perspective is that of the State. The Department will offer a more detailed response 60 days after the release of the report and CLTAC will have an opportunity to make recommendations to the Department. He asked people to contact himself of Mr. Thomas if there is a particular recommendation that a CLTAC member would like the CLTAC to respond to.

Dr. Hilborne said that he thought clarity on the audit would aid recruitment and offer assurance on job security.

Ms. Becker asked Dr. Kimsey if the CLTAC would be able to see the 60 day response before the next meeting.

Dr. Kimsey replied in the affirmative and noted that the 60-day response would go to the auditors in November, and the finished response would be included in the members' December packets.

Legislation updates

Ms. Wogec reported that it had been a robust legislative season for LFS. She reported that LFS had three large complex bills, one small bill, one bill resurrected from the previous season, and one trailer bill, which Dr. Kimsey discussed in his report. She explained that trailer bill language is the implementing language of the California State Budget Bill. Trailer bills do not require the level of analysis that regular bills require. Usually only one section of a trailer bill will affect LFS. She clarified that the minutes of the June meeting referred to an Assembly trailer bill (AB 94). There were two trailer bills, AB 94 in the Assembly and SB 75 in the Senate. It was the senate version that

passed.

She reported that the other bills analyzed by LFS were more complex and time consuming. She noted that when LFS analyzes a bill, unless the bill is sponsored by the Department, LFS does not take a position until the Governor takes a position. LFS staff members provide an internal analysis for the Governor's office, which is forwarded through the Office of Legislative and Governmental Affairs (LGA), but LFS does not share its recommendations. The Governor decides whether he will accept that recommendation or not.

The first bill, AB 258, concerns organ transplants for medical marijuana patients. The author was Assemblymember Mark Levine, State Senator Mark Leno was the principle co-author, and State Senator Loni Hancock, Assemblymember Mike Gipson, Assemblymember Reginald Jones-Sawyer, and Assemblymember Bill Quirk were co-authors. It was sponsored by Americans for Safe Access.

AB 258 would add Section 7151.36 to the Health and Safety Code to prohibit California transplant centers from disqualifying the recipient of an anatomical gift based solely upon a potential recipient's status as a qualified medical marijuana patient, or based solely upon a positive test for the use of medical marijuana by a potential recipient who is a qualified patient, except to the extent that the qualified patient's use of medical marijuana has been found by a physician and surgeon, following a case-by-case evaluation of the potential recipient, to be medically significant to the provision of the anatomical gift. The prohibition requirement adds to the Uniform Anatomical Gift Act.

The bill had extensive support and no opposition. AB 258 was introduced on February 9, 2015, and was amended on March 25, 2105. It was enrolled on June 24, 2015, and signed by the Governor and chaptered on July 6, 2015 (Chapter 51, Statutes of 2015). Jan Otey worked on the bill for LFS.

AB 599 concerns the scope of practice of cytotechnologists. It was authored by Assemblymember Susan Bonilla and sponsored by the California Association of Cytotechnologists and the California Society of Pathologists.

AB 599 would amend BPC §1270 to expand the scope of practice of licensed cytotechnologists. The bill would authorize a licensed cytotechnologist to perform all tests and procedures pertaining to cytology, including microscopic and non-microscopic methodologies and tests and procedures that utilize molecular or genetic methodologies that are performed on cytologic specimens related to infectious disease or cancer diagnosis under the overall operation and administration of a laboratory director, subject to specified requirements.

AB 599 had extensive support and was opposed by the Engineers and Scientists of California and numerous individuals. AB 599 was introduced in February 24, 2016. It was amended three times on April 6, 2015, May 28, 2105, and on August 24, 2015. It was passed without opposing votes and was enrolled on September 4, 2015, and is

awaiting the Governor's decision.

Responding to a question, Ms. Wogec confirmed that while bills undergo numerous revisions, her summaries were for the most recent versions of the bill.

AB 757, concerning the scope of practice in plasma collection facilities, was authored by Assemblymember Jimmy Gomez and was sponsored by Grifols, Inc. AB 757 was supported by various plasma companies while opposition came from various professional associations.

AB 757 would amend BPC §1246.7 to make an exception to current California law to allow unlicensed individuals who meet specific standards to perform a total protein refractometer test (TPRT) in a licensed plasma collection facility in California. The provisions of the bill would sunset on January 1, 2019.

Ms. Wogec reported that Mr. Hunter had done most of the work on this complicated bill, and she would defer to his later presentation.

AB 757 was introduced on February 25, 2015, and was amended three times, on March 26, 2015, April 30, 2105, and June 22, 2015. It has passed both the Assembly and the Senate and was enrolled on September 2, 2015. It is now awaiting the Governor's decision.

AB 940 concerns clinical laboratory directors. It was authored by Assemblymember Sebastian Ridley-Thomas, co-authored by Assemblymember Marie Waldron, and was sponsored by the California Clinical Laboratory Association.

AB 940 began as a modest bill amending five sections of the BPC. It was amended several times to involve up to eleven sections of the BPC before ultimately reverting to its original size. AB 940 as currently written would amend five sections the BPC. It would delete the requirement that a laboratory director substantially meet the laboratory director qualifications under CLIA (that is, the word "substantially" would be deleted). It would amend the definition of laboratory director to require that one laboratory director must meet the qualifications of the federal Clinical Laboratory Improvement Amendments (CLIA), and to allow a bioanalyst qualified under CLIA to serve as a laboratory director in addition to the CLIA-qualified director in a laboratory performing high complexity testing. It would allow an applicant for bioanalyst licensure to obtain the experience required for California licensure in an out-of-state laboratory certified under CLIA rather than a laboratory approved by the Department. It would authorize license renewal fees for clinical cytogeneticists and clinical molecular biologists and would make other minor clarifications. Robert Thomas did much of the work for LFS on this bill.

AB 940 is supported numerous associations and has no opposition. It was introduced on February 26, 2015, and was amended five times (March 23, 2015, April 23, 2105, July 1, 2015, July 14, 2015, August 20, 2015) since it was introduced in February. It

passed both the Assembly and Senate without opposition and was enrolled on September 4, 2015. It is now awaiting the Governor's decision.

Beatrice O'Keefe asked if AB 940 allows for license fees for new license categories.

Ms. Wogec responded that the current version would not allow for that.

SB 622 concerns the scope of practice of optometrists. Ms. Wogec thanked Dora Goto, representing the CAMLT, who brought this bill to LFS' attention.

She reported that SB 622 was the resurrection of SB 492 from the 2013-2014 legislative season, which was a two year bill that it died. SB 622 is almost the same as the previous version. Both bills were authored by Assemblymember Ed Hernandez.

SB 622 would amend ten sections of the BPC to delete current requirements under the Optometry Practice Act that specify circumstances under which optometrists must refer patients to an ophthalmologist or a physician and surgeon. It would replace these specific requirements with a broad requirement to refer any patient when a situation or condition occurs that is beyond an optometrist's scope of practice.

SB 622 would allow an optometrist to perform minor procedures and use specified nonsurgical techniques after meeting post-doctoral education requirements and performing procedures on live humans to demonstrate competency. It would additionally authorize an optometrist certified to use therapeutic pharmaceutical agents to collect a blood specimen by finger prick method, and also to perform skin tests, as specified, to diagnose ocular allergies. It would allow an optometrist to initiate and administer vaccines for influenza, herpes zoster, and pneumococcus after meeting certain requirements. It also states an uncodified intention to establish a pilot project to test, demonstrate, and evaluate expanded roles for optometrists in the performance of management and treatment of diabetes mellitus, hypertension, and hypercholesterolemia.

SB 622 has some support but also considerable opposition. Ms. Wogec noted that only a small section of the bill affects LFS, and the LFS analysis only addressed the sections of concern to LFS. Other programs, agencies, and departments are also working on it. Jan Otey worked on this bill for LFS. SB 622 was introduced on February 27, 2015, and amended twice on April 9, 2105, and May 4, 2015; it has now become a two year bill.

Ms. Goto stated CAMLT's opposition to the bill, saying that in its current form, SB 622 would permit optometrists to order any laboratory test that has ocular effects, noting that currently they can only order from a finite list defined by BPC §3041. She added that if it is a waived test, not only could they order it, but they would also be able to perform it.

Ms. Becker asked if there were any questions or comments.

Shannon Smith-Crowley asked if Ms. Wogec had said that Grifols was the manufacturer

of the refractometer or the user.

Ms. Wogec said that they were the manufacturer. Ms. Smith-Crowley replied that they were not. She stated that Grifols collect plasma to make blood products and they use this device, which has a CLIA medium complexity rating.

Ms. Becker asked if Mr. Hunter would like to comment.

Mr. Hunter stated that Ms. Smith-Crowley was correct. The sponsor, Grifols, is a manufacturer of plasma products and not the instrument manufacturer. Ms. Wogec agreed and apologized for misspeaking. Mr. Hunter thanked Ms. Wogec for her presentation and noted that his Power Point presentation on AB 757 providing the wording of the bill was available in the meeting handouts.

Ms. O'Keefe commented that she had reviewed the package information on the refractometer. She said that it is a moderate complexity test and requires calibration, which cannot be performed by unlicensed persons in California. Ms. Goto stated that CAMLT is actively opposing the bill.

Mr. Thomas noted that AB 940 changes current law slightly, allowing for one laboratory director who must be a CLIA-qualified director, but also allowing for additional laboratory directors. This is one difference between CLIA and California law, which lists multiple directors on a laboratory license, who can use their expertise in assisting with specific areas of a laboratory.

Dr. Hilborne asked if, from the federal perspective, the CLIA certificate holder is accountable.

Mr. Thomas deferred to Ms. McCallum, but noted that in his understanding only one director is recognized by CLIA.

Ms. McCallum agreed that CLIA only recognizes one director. She explained that when a laboratory applies and submits a list of directors for State licensure, they indicate in the packet which director will serve as the CLIA director and that person must meet the requirements.

Draft review of CLIA Changes of 2003 and California Law

Kathy Williams, Section Chief of Facility Licensing in northern California, presented the report of the CLTAC Subcommittee on CLIA 2003 as a chart. She said that even though the subcommittee was not charged with reviewing sections that referred to requirements of greater or equivalent stringency, they decided to do so, which explains why the report is so long.

She explained that the chart consists of three columns. The left column contains the language of CLIA of 2003. The middle column contains California law, which incorporates CLIA of 1994, and so it contains CLIA numbers as they had already been

adopted into law. The right column contains the subcommittee's evaluation of stringency and a recommendation whether or not a section from CLIA should be incorporated into California law. The right column presents two sets of codes, the first initial indicating the stringency of the change, standard, or condition, the second initial indicating the subcommittee's recommendation. For the first set of initials, "M" indicates more stringent, "E" indicates equivalent stringency, and "L" indicates less stringent. The second set of initials indicates the recommendation for action to be taken. "M" items automatically go into effect as an operation of law (OOL), while "E" and "L" items have the option of being adopted (A) or rejected (R).

She reported that of the 75 changes listed only three of those that were less stringent were rejected. The first was the substitution of a photographic chart for urine sediments rather than requiring a wet control. The second concerned titered-out tests such as syphilis serology (Appendix E); CLIA 2003 switched from concurrent with patient testing to testing once a day, and the subcommittee felt that was not appropriate, they wanted to keep the concurrent titer as the control. The third removes the requirement to post safety charts, and the subcommittee felt it was important to keep the posting.

Ms. Williams reported that the full report is now being presented to the stakeholders and the full CLTAC based on recommendations of the subcommittee. The full CLTAC now needs to vote on their recommendation and inform the department, and the department will make a final decision as to what goes into rule-making and what goes automatically into law.

Dr. Geisse asked if safety posting is already covered by Cal OSHA regulations. Ms. Williams said that it is.

Dr. Hilborne asked if a federal law is more stringent than a California law, should the California law not be eliminated. He also noted that the chart states that item 493.1105(a) was determined to be as stringent or more stringent, but the individual items in Appendix A referenced by the item varied in their stringency, some being less stringent. Because this seemed to invalidate the subcommittee's decision to categorize the item as "M" or "E" he could not vote to approve the whole as the parts were problematic.

Ms. Williams responded that individual items in Appendix A that are more stringent would automatically take precedence, equivalent items would take precedence, and less stringent items are optional.

Mr. Hunter commented about the immunohematology section in Appendix A, noting that those are not the AABB requirements. The retention times for California need to be referred to the AABB records retention requirements, and they are longer than CLIA and in some cases they are less.

Dr. Geisse reported that he had gone through the summary in detail and thought that CLTAC/California should defer to the federal law's less stringent requirement that tissue

remnants be allowed to be kept for three year versus until the diagnosis is made by the federal law.

Ms. Schiffgens recommended that further discussion should be held during the next meeting, since a lot of time had gone into the report but CLTAC members had not had sufficient time to review it.

Ms. Pahland commented that the Department is charged with following BPC §1208, which allows the Department to simply adopt CLIA 2003 where it is equivalent to or more stringent than California law. She also reported that the Department was hoping for a vote by the CLTAC that would provide their official advice, which the Department would take under advisement, so the Department could proceed with providing a notice in the register. She reiterated that while the chart would require some editing, the CLTAC should vote on the determinations. Once there was a notice of what is more stringent or equally stringent, the group could look at those items that are less stringent and make a determination as to which of the less stringent ones should be accepted or rejected.

Ms. Williams added that part of process is to harmonize federal and State QC requirements.

Mr. Thomas commented that the Department was hoping for a vote and a conclusion on the charge that was made some years ago so it could move forward.

Ms. McCallum agreed, noting that there were other items not in the report that were provided as appendices that could be dealt with later.

Ms. Doty commented that the CLTAC should not redo the work that the subcommittee spent years doing. She moved that the CLTAC adopt the determination of more stringent or equivalent recommended by the subcommittee. Dr. Geisse seconded the motion.

Ms. Shiffgens asked if that would be a vote to default to the CLIA regulations presented in the chart and not follow state law.

Ms. Pahland said essentially yes, as the current California law would be replaced by the CLIA regulations, but it would not be automatic, but would happen after the notice is published and agreed upon.

Mr. Thomas explained that once the CLTAC made its recommendation, the Department would take it as advisory, but the Department would make the final determination.

Ms. Pahland added that BPC §1208 requires the interaction of CLTAC and LFS for this determination, so CLTAC’s recommendations are highly persuasive to LFS.

Dr. Hilborne reiterated that because there were discrepancies with the individual items

within a given regulation, he could not vote on the whole as it might pass into law those items that were inaccurately categorized in the report.

Ms. Pahland commented that the committee should look only at those items that are of greater or equivalent stringency. Those that were less stringent would appear in another package.

Ms. Doty agreed with Ms. Pahland, stating that the motion stated that CLTAC should adopt the stringency recommendations. In order for the CLTAC to move forward, they could adopt the recommendations for stringency.

Ms. Pahland asked if the CLTAC could amend the motion, as it appeared the committee agreed with all but one of the items.

Elsa Eleco, an examiner in the LFS CLIA program, noted a typo in Appendix A: in the federal section, retention of cytology reports should be 10 years, not 2 years, and retention of histopathology reports is 10 years, not 2 years. Cytology and histopathology are subspecialties of pathology; therefore, it is 10 years.

Ms. Doty reported that as the issue was that items in Appendix A did not match the determination of stringency, the motion should be voted down rather than amended.

Dr. Hilborne suggested the committee approve the document in principle and then allow for a 30 day period to comment on it.

Ms. Becker called for a vote. The vote was 5 for, and 6 against.

Dr. Hilborne motioned that the CLTAC accept the report of the subcommittee in principle to acknowledge that there was general agreement with most of the determinations with respect to stringency. He suggested that this would give the committee members and the regulated community time to review the document for discrepancies and notify the Department, and then the Department could determine whether they agree with the comments of the community or if they wish to bring them back to the CLTAC for discussion. Ms. Schiffgens seconded the motion.

Ms. Pahland commented that in the end, the CLTAC needed to take an official position, and the record would need to show it. She recommended that the motion be amended to include an agreement that the chart as presented was the position of the CLTAC because that will have to be included in the register of record that the items were registered due to the coordinated effort of CLTAC and LFS.

Dr. Hilborne replied that if the errors could be resolved in the interim through comments to the Department, a vote on the whole could be held at the next meeting.

Ms. Schiffgens noted that she was not prepared to vote on the whole document as there were still questions about the accuracy of some of its parts.

Ms. Becker commented that she expected many of the discrepancies to be corrected during this phase and that the comments and the day's discussion would aid in the correction of the document.

Mr. Thomas noted that it would be problematic for the Department to receive comments directly from the general public about errors in the chart as that might lead to endless revisions. He suggested the public contact the CLTAC members; they would then pass those comments to the chair, who would then notify the Department.

Dr. Hilborne suggested that 30 days would be enough time for the comment period, and since there was general agreement with most of the report, a special session or email vote could be held to clear up minor errors.

Ms. Becker suggested that during the 30-day period, comments and questions go to her, and she would distribute them to all the CLTAC members and they would vote on what they received. Final comments would go to LFS so they could work on it before the December meeting.

Barbara Brunell commented that while typos could be corrected, she did not think the CLTAC could rework what the subcommittee took years to produce.

Ms. Williams responded to a concern that the report did not represent the subcommittee's findings, noting that the report not only represented their findings, it was their consensus, and the report was essentially their position paper.

Ms. Schiffgens suggested that the CLTAC look at the whole document and not just stringency as the December vote would be to accept or reject the whole document.

Dr. Hilborne referred to the chart, noting that items designated "M" and "E" would be OOL, and the CLTAC could revisit those designated less stringent later, while still maintaining focus on what needed an immediate answer.

Ms. Schiffgens noted that she believed both were needed in December.

Ms. Pahland asked if this chart should excise those that are less stringent.

Dr. Hilborne said that although it might be helpful to split the categories for the purpose of discussing on each item, the CLTAC could approve the more stringent and equivalent items and discuss the less stringent items later.

Ms. Pahland noted that by splitting the chart into two, and approving the more stringent and equivalent items, the CLTAC would also imply agreement that those in the other chart were less stringent.

Ms. Becker commented that she did not think separate charts were needed. What was

needed was stringency determination, which was included in the current chart.

Dr. Hilborne agreed.

Ms. Becker reported that there was still a motion on the floor. A vote was taken and the motion passed unanimously.

Changes to the online application system

Ms. Kruthoff reported that the new personnel licensing system, PERL, was expected to go online on June 30, 2015, but due to ITSD delays on the part of both the vendor and CDPH, that date was extended to September 28, 2015. She reported that the department was on track to go live on that date.

Ms. Kruthoff reported that some significant changes are coming to LFS' database system that would improve service and turnaround time. Applicants will be able to upload some documents directly into the electronic system, although transcripts, which must be certified and sealed, will still need to be mailed. The management system will allow for the generation of automatic reports. Once those documents that cannot be uploaded are received by LFS, they will be scanned and uploaded electronically to the applicant's file in the PERL system. She added that scanners were slated to arrive on September 15, 2015. LFS anticipates that this will reduce the amount of time necessary for review and approve applications.

She reported that LFS is moving to a system of group email boxes that will allow multiple staff to view emails. Emails will also be a part of the PERL system, so all correspondence will link automatically to an applicant's file.

She reported that the needs of the renewals program are being addressed, and that she is working with the Department's contract management unit to finalize a contract. Once that has been done, it will go out for bid, a contractor will be chosen, and the creation of a new database system for renewals will begin.

She reported that the CSA report strongly recommended that LFS implement an online system for facilities licensing. LFS needs to know when it receives applications and how long it takes to process those applications, and needs to put everything online. ITSD will first do a feasibility study, and that process will start within the following six weeks. Once the feasibility study is completed, the contract process and selection of a contractor can begin. ITSD anticipates that the facility licensing process can be completed in two years.

CLIA Update

Donna McCallum, Section Chief of the CLIA Section in Los Angeles, emphasized that IQCP is a collaborative effort involving CMS and the CLIA program. She reminded the meeting that IQCP will be the only QC option after December 31, 2015. Prior to that date, EQC is allowed during the educational period from January 1, 2014, to December 31, 2015.

Ms. McCallum responded to an earlier question about how surveyors would be prepared for inspecting IQCP. She reported that in November of 2013, there was an in-depth training in Baltimore before the IQCP documents were released to the public. There was also a webinar for CLIA surveyors, later made available to the public. There are three brochures on the CMS CLIA website, numbers 11, 12, and 13, that relate to IQCP, as well as an IQCP workbook to assist laboratories to develop an IQCP plan for their own individual test systems. The workbook includes scenarios and step by step applications on how the process can be modified to meet a laboratory's demands. She explained that IQCP involves both QC and QA. She noted that when CLIA inspectors look at risk assessment, they look at the specimen, test, reagents, environment, and the testing personnel.

She reported that as of July 2015 the total number of compliance laboratories posted on the CLIA website was 18,505, there were 174,122 waived laboratories, 35,150 PTMT laboratories, and 16,431 accredited laboratories. Of that number, California's totals were 1,553 compliance laboratories, 15,137 waived, 3,231 PTMT, and 1,235 accredited facilities. She noted a slight drop in the number of accredited facilities.

She reported that the CLIA section was still short one surveyor and would have an opening in the near future for a surveyor. However, based on statistics for the year of 2014, during which 735 surveys were completed, she anticipated completing the majority of the surveys by the end of the State fiscal year, noting that by August 2015 they had completed 779 surveys.

Facilities Licensing Section Update, Richmond

Kathy Williams, Section Chief of Facility Licensing in northern California, reported on facilities licensing statistics, noting that complaint allegations were not included. Twenty seven complaints were received in the last three months. Three complaints concerned test management and quality assurance, 3 concerned facilities licensing, 11 concerned personnel (1 CLS, 7 phlebotomists, 2 unlicensed personnel, 1 other), one concerned fraud associated with unauthorized testing, 3 were miscellaneous, and 6 other complaints were referred to other programs and agencies, including the Medical Board, CLIA, and Licensing and Certification.

She announced that Shideh Khashe, an examiner who was set to retire August 10, has returned to LFS. She is handling the out-of-state licensing, replacing Gwen Wong, who retired on August 31. Pat Toomer, the proficiency testing examiner, is out of the office indefinitely, and Howard Manipis, a retired-annuitant who works in out-of-state licensing, is also out indefinitely. She reported one new employee, Johnny Sanchez, who comes to LFS from the Franchise Tax Board, and will be working as receptionist and data entry person.

Facility Licensing Section Update, Los Angeles

Victoria Maxwell, Examiner II of Facility Licensing in southern California, introduced Catherine Tolentino, who joined the team on August 17th. Ms. Tolentino earned a

degree in medicine in the Philippines and came to the United States in 2008; she received her CLS license in 2009, and came to LFS from private reference laboratories in Los Angeles.

Ms. Maxwell reported that in the second quarter of 2015 her section received 29 application packets from Richmond. Fourteen of these were surveyed within the second quarter of 2015 and 15 were pending survey; she expects these to be completed by the end of the third quarter of 2015. For the second quarter of 2015, a total of 20 laboratories have been surveyed; 45% were cited for deficiencies and 55% received no deficiencies.

She reported that seven accredited laboratories were surveyed in the second quarter of 2015; 86% of the laboratories surveyed had deficiencies and 14% received no deficiencies. She noted that due to a personnel shortage initial inspections have been given priority.

She reported that four complaints were received and processed in the second quarter. One was referred to Richmond and three were investigated. One involved the use of unlicensed personnel, the second involved delay in specimen processing and testing, and the third involved test results error. The first two complaints were substantiated and the last was not.
She reported that six out-of-state (OOS) laboratories were surveyed in the second quarter of 2015; 50% were cited for deficiencies and 50% received no deficiencies. Four of the laboratories were accredited by CAP and two by AABB. She hopes to inspect 12 more OOS laboratories by the end of the fourth quarter of 2015.

Personnel Licensing Section Update

Zahwa Amad, Ph.D, Section Chief of the Personnel Licensing Section, introduced a new Examiner II, Dolapo Afolayan, who joined LFS on July 1 from the Virus and Rickettsial Disease Laboratory of the Richmond campus. She has bachelor of science degree in microbiology from UC Davis, a master's degree in Health Education from San Francisco State. Dr. Amad reported that LFS has an open position in the phlebotomy program for an Examiner II who would be in charge of phlebotomy training schools. She thanked Blesilda Honorio, supervisor of the renewal program, who, along with Ms. Kruthoff, stepped in to reallocate resources to renewals to improve turnaround time.

She reported, that with regard to statistics, a total of 607 MLTs have been licensed by LFS since the program was initiated in 2007.

She reported that it was still quite common for the renewals program to receive last minute applications from people who needed their licenses within a few days; she also reported that LFS still receives numerous returned mails because many people fail to update their mailing addresses with LFS within the 30 days mandated by regulations. She urged stakeholders talk to their staff about the two issues.

She thanked Ms. Wogec for placing frequently asked questions for renewals on the LFS

website. She noted there is also a renewals and continuing education webpage that has a checklist and links to renewals forms.

She reported that renewals program is planning to implement the use of hand scanners the following week, which should increase staff productivity, adding that the new system would improve things even more as all would be online.

Tissue Bank and Biologics Update

Ron Harkey, Section Chief of the Biologics and Tissue Bank Section, reported that the lion's share of all the bills analyzed by LFS in 2015 had been handled by the Tissue Bank and Biologics Section. It takes from one to three weeks of full time work to produce a bill analysis, in addition to responding to further questions. In addition, staff must respond to other questions. As an example, he cited a blitz of questions after recent news stories about Planned Parenthood.

He noted that the statistical report on the Tissue and Blood Bank Section was meant to provide a background and Mr. Hunter would give the report on the Biologics section, as his statistics for that area were not included.

Mr. Hunter thanked everyone who had comments on AB 757. He said he wished to recognize Mr. Harkey, Ms. Wogec, and Sheena Nash of LGA for their assistance with his analysis.

New business

Ms. Becker thanked Mary Wogec, Nai Saechao, Donald Miyamoto, and Dennis Tavares for their assistance with preparations for the northern California meeting and support with audio visual communications between the southern California and northern California meetings. She also thanked LFS staff for their work in preparing for meetings.

Ms. Becker asked if anyone had new business to discuss.

Mr. Thomas noted that digital pathology appears frequently on the agenda, and asked if it was something that should be addressed in the future.

Ms. Becker noted that a previous guest speaker, Dr. Jared Schwartz, gave a very thorough technical presentation on digital pathology at the September 2014 meeting and she thought the follow-up should address questions about how digital pathology would be inspected. On the suggestion of Dr. Hilborne, she agreed to look for a pathologist engaged in digital and ask how inspection teams from the College of Pathologists approached issues of quality control, quality assurance, and quality improvement. She noted that guest speakers would be added as the agenda allowed.

Next meeting

Ms. Becker announced that the next meeting of the CLTAC would be held on Friday, December 4, 2015.

Adjournment

Dr. Hilborne moved that the meeting be adjourned, the motion was seconded by Mr. Geisse, and the CLTAC board voted to adjourn at 12:40 p.m.